EXHIBIT N

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

AFFIDAVIT OF SHELBY F. THAMES, Ph.D.

STATE OF MISSISSIPPI

COUNTY OF LAMAR

PERSONALLY APPEARED BEFORE ME, the undersigned authority in the aforesaid county and state, the within named Dr. Shelby F. Thames, who first being sworn states:

1. My name is Dr. Shelby F. Thames. I am over twenty-one (21) years of age and of sound mind and body. I have knowledge of, and am competent to testify about, the matters stated in this Affidavit. I am under no legal or other disability. The facts stated herein are true and correct to the best of my knowledge and belief.

2. I earned a Ph.D. in Organic Chemistry in 1964. My research has focused on organic polymer chemistry, which includes organic coatings, my entire career. In 1969, I founded the Department of Polymer Science at the University of Southern Mississippi and have served as a tenured professor for Polymer Science graduates since that time. Prolene, the material from which Ethicon's mesh products are made, is a thermoplastic polymer and, as such, has been a part of my classroom teachings.

Overview

3. I was asked to opine about whether Prolene oxidizes *in vivo*. In reaching my opinions, I have cleaned and analyzed Prolene mesh explants during the course of this litigation, including 20 explants from the MDL Wave 1. My analyses of the explants thus far confirm no oxidation has occurred *in vivo*.

4. I have reviewed Plaintiffs' Memorandum in support of their motion to exclude my opinions (Doc. 2042). I am submitting this Affidavit to address the basic chemistry and scientific principles for two issues that Plaintiffs raise about the cleaning process: (1) whether intentionally oxidized Prolene was needed as a control; and (2) whether Proteinase K removed oxidized carbonyl bands. In short, for the reasons explained below, intentionally oxidized Prolene was not needed as a control and Proteinase K does not remove oxidized carbonyl bands. Plaintiffs have provided no scientific evidence that supports their position on either issue.

The Mesh Explant Cleaning Process

5. In order to conduct a proper analysis, sound scientific principles dictate that mesh explants must be cleaned of any adhered biological materials, such as proteins. This involves removal of proteins that adhere to the mesh fibers immediately upon and during implantation. As discussed below, the failure to remove proteins prevents a scientifically valid analysis that can determine whether the mesh fibers oxidized *in vivo*.

6. It is undisputed that explants are covered with proteins after they are removed from the body. It is also undisputed that these protein-covered explants were preserved in formalin (which contains formaldehyde) after explantation. Basic organic chemistry confirms that a chemical reaction occurs when proteins are exposed to formalin. The chemistry of formalin fixation of proteins has been known since 1949, and the characteristics of the fixation

are described in the scientific literature.[1] It is also well-established in the scientific literature that adsorbed proteins must be removed before studying an explant.[2] Accordingly, the cleaning process that I used accounts for the formalin fixation of proteins.

7. There is no ISO-certified cleaning process for mesh explants. Thus, I used my knowledge of basic organic chemistry regarding the formalin fixation process. It is a reversible reaction. This is important because a water molecule is released during the fixation process in order for formalin to react with proteins. Thus, if one places a formalin-fixed explant in a water-based solution, the reaction is reversed, allowing the formalin/protein coating to be "un-fixed" or removed.

8. The cleaning process that I used is outlined in my expert reports. In summary, it involves placing a formalin-fixed explant in distilled water, heated to 70° C, and then adding sodium hypochlorite (bleach) and Proteinase K (an enzyme). The result of this mild cleaning process is an explant that is now "cleaned" of proteins that were previously adhered to its surface. This cleaning process is the mildest effective cleaning regime of which I am aware.

Analyses of Mesh Explants

9. Plaintiffs argue that "Dr. Thames did not run a control of purposefully oxidized polypropylene through his cleaning protocol to test if it would destroy evidence of oxidation." Memorandum p. 9. Plaintiffs do not support this contention with any scientific evidence or an

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[1] Fraenkel-Conrat, Heinz. and Mecham, Dale, K., The Reactions of Formaldehyde with Proteins VII., Demonstration of Intermolecular Crosslinking by Means of Osmotic Pressure Measurements, J. Biol. Chem., 1949, 177:477-486; Fox, Cecil H., Johnson, Frank B., Whiting, John, and Roller, Peter P., Formaldehyde Fixation, The Journal of Histochemistry and Cytochemistry, Vol. 33, No. 8, p. 845-853, 1985. See also Dr. Susan Lester's Manual of Surgical Pathology, 3rd Edition, 2010 (explaining the fixation process and describing the fixed product as hard, insoluble, and brittle).

[2] Ze Chang, M.W. King, T. V. How, G. Laroche and Robert Guidoin in Biomaterials 1996, vol 17, no. 19. "In order to study the surface chemistry of explanted prostheses, it is necessary to remove all the tissue that may have grown over and within the prosthetic structure. In the event that the explant has been treated with a fixative agent after retrieval, such as formaldehyde or glutaraldehyde, the tissue will be crosslinked and the only effective way of completely removing it is to use hydrolytic chemicals."

affidavit from an expert in the relevant field. A control using intentionally oxidized Prolene was unnecessary. As I explained in my deposition, the cleaning process "uses mild conditions" and is a "reversal of basic chemistry."[3]

10. Had I been asked at deposition about the basic chemistry, I would have explained that the cleaning solution (distilled water, bleach and Proteinase K) only removes water soluble materials. Proteins are water soluble; oxidized materials of Prolene origin are insoluble in water. Thus, the cleaning solution utilized will only remove water soluble materials (i.e. proteins) and not water insoluble materials (i.e. oxidized Prolene).

11. An experimental control is necessary to control variables. The solubility characteristics of the materials at issue is basic chemistry and not a variable concept. Controls are unnecessary to prove basic chemistry concepts.

12. Plaintiffs also argue that my interpretation of the FTIR results failed to consider the effect that Proteinase K had on potentially oxidized Prolene. Specially, Plaintiffs state "According to Dr. Thames, Proteinase K takes away carbonyls, but carbonyls are also what would be present on the mesh if it was oxidized." Memorandum, p. 10. As I explained in my expert report, I analyzed the explants, as well as a Prolene exemplar control, using Fourier Transform Infrared Spectroscopy (FTIR), Scanning Electron Microscopy (SEM), and Light Microscopy at each step of the cleaning process. These are standard analytical techniques that are well known and recognized by chemical and forensic scientists. I used these techniques to ensure that any chemical changes, including oxidation, of the Prolene fibers would be found and documented.

[3] Dr. Thames General Depo. at 62:10-23.

14. A FTIR machine produces a spectrum of a material's "chemical fingerprint." Scientists then use that spectrum to study carbonyl bands, or "peaks," which show the chemical make-up of the material at issue.

15. Plaintiffs are using the term "carbonyls" in a very generic sense that misrepresents the chemistry. FTIR spectra may include many different types of carbonyl bands, such as amides, esters, ketones, aldehydes, some of which can show oxidation. Importantly, however, carbonyl bands also show other materials present on the surface, such as proteins, which are amide groups. Thus, while Proteinase K does indeed "take away carbonyls," ***it removes protein carbonyls, not oxidation carbonyls***. That is a critical distinction. Plaintiffs are simply confused as to which carbonyl bands were removed during my cleaning process.

16. Had I been asked at deposition *which* carbonyl bands were impacted by Proteinase K, I would have explained that *protein* carbonyl bands are reduced and ultimately eliminated. Neither Plaintiffs' counsel nor their experts have submitted any scientific support establishing that Plaintiffs' use of the term "carbonyls" in a generic fashion is scientifically appropriate. Basic chemistry dictates that they cannot.

17. Proteins possess carbonyl bands.[4] Proteins are water soluble and that is why they can be removed by the cleaning process. If the explants had oxidized, oxidation carbonyl bands would have formed and the oxidized layer would be insoluble in water and not lost during the cleaning process. Thus, if an oxidation carbonyl band was present, FTIR would have shown it after each cleaning step. In these cases, the only carbonyl bands shown are ***protein*** carbonyl bands, not ***oxidation*** carbonyl bands.

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[4] See J. Kong, Fourier Transform Infrared Spectroscopic Analysis of Protein Secondary Structures, Institute of Biochemistry and Cell Biology, March 2007.

18. As stated above, I intentionally removed proteins to analyze the cleaned explants for oxidation. The cleaning process used Proteinase K, an enzyme that denatures proteins, making them easier to remove. As the name implies, "***Protein***ase K" affects proteins, not oxidized material.

19. The FTIR spectra taken of these explants after each cleaning step show that Proteinase K worked as intended: the ***protein*** carbonyl bands decreased after each step and were ultimately eliminated to the extent the cleaning process permitted; the explants never had ***oxidized*** carbonyl bands. Likewise, the FTIR analyses of the Prolene ***exemplar*** after each cleaning step shows that it did not contain either protein carbonyl bands or oxidation carbonyl bands. Thus, it never had proteins on its surface, and was not oxidized.

20. All these data were made available to Plaintiffs in my expert reports.

FURTHER AFFIANT SAITH NOT.

Dr. Shelby F. Thames

SWORN TO AND SUBSCRIBED before me this the 9th day of May, 2016.

NOTARY PUBLIC

My Commission Expires:

Aug 2, 2018

STATE OF MISSISSIPPI NOTARY PUBLIC ID # 96660 KIMBERLY HARRIS BRANDON Commission Expires Aug. 2, 2018 LAMAR COUNTY